

REMARKS

The present response is submitted in reply to the Office Action issued on July 2, 2008.

Claims 1-7 are pending in this application, all of which have been rejected. By the present response, claims 1 and 2 have been canceled and claims 5, 6 and 7 have been amended. No new matter has been added. Reconsideration is respectfully requested in light of the following remarks.

Rejection of claims 1-2 and 5-7 under 35 U.S.C. 101

Claims 1-2 and 5-7 have been rejected under 35 U.S.C., 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim. The Applicants submit that claims 1 and 2 have been canceled and claims 5-7 have been amended accordingly. Withdrawal of this rejection is respectfully requested.

Rejection of claims 1-7 under 35 U.S.C. 112, first and/or second paragraphs

Claim 5 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner states that within the structure given in the claim, the "O" at the 14 position of the ring structure does not have a substituent indicating the addition of a group. The Examiner further states that claim 6 further limits claim 5 and the "O" at the 14 position is connected to a group or formula. The Examiner requests that the Applicants complete claim 5 by putting another "R" group to exemplify the invention.

Claims 1-7 have been rejected under 35 U.S.C. 112, first paragraph, on the basis that the specification does not reasonably provide enablement for treating diseases mediated by *Helicobacter pylori* and in particular chronic gastritis. The Examiner further states that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicants respectfully request that the aforementioned rejections be withdrawn, as discussed below.

Regarding the indefinite rejection of claim 5, the Applicants submit that claim 5 recites a pleuromutilin in more detail in that a structural part thereof is unambiguously defined. The Applicants submit that neither a pleuromutilin, nor a structural part thereof, should be considered to be indefinite since one skilled in the art would clearly be aware what a pleuromutilin is.

Regarding the rejection of claims 1-7 as being indefinite, the Applicants submit that it has been shown by experimental results as set forth in the present specification (such as at paragraphs [280] – [288], for example) that quite different antimicrobially active pleuromutilins in very low concentration, e.g., in much lower concentration than prior art compounds, inhibit the activity of 5 different *Helicobacter pylori* strains. It is furthermore shown that pleuromutilins even show activity against strains which are practically metronidazole-resistant, such as strains *Helicobacter pylori* strain ATCC number 43504 and *Helicobacter pylori* strain ATCC number 43629.

It is submitted that the prior art compounds which were used for comparison according to the present application are the antimicrobials metronidazole and tetracycline.

These compounds are used for eradicating *Helicobacter pylori* activity and are recommended for first-line therapy for *Helicobacter pylori* infections (see e.g., T. Rokkas, *Annals of Gastroenterology* (2005), 18 (2), pages 119 – 126, left column, second paragraph, and together with “The Maastricht 2-2000 Consensus Report” which is e.g., commented by P. Malfertheiner, et al., in “*Alimentary Pharmacology & Therapeutics*,” Vol. 26, Issue 2, pages 167-180, published online January 18, 2002 (copy enclosed)).

It is thus evident that compounds which influence the activity of *Helicobacter pylori* contribute to the treatment of diseases which are mediated by *Helicobacter pylori* (infection). Therefore, if the compounds of the present invention show activity in inhibiting the activity of *Helicobacter pylori*, one skilled in the art has a reasonable expectation that these compounds are also appropriate for the treatment of diseases which are mediated by *Helicobacter pylori* (infection), such as metronidazole and/or tetracycline. Moreover, in view of the fact that the compounds of the present invention show much lower MIC's than metronidazole and tetracycline, one skilled in the art has a reasonable expectation that the compounds of the present invention are surprisingly even much more appropriate than the compounds of the prior art tetracycline and/or metronidazole, i.e., particularly against *Helicobacter pylori* strains which are metronidazole-resistant.

It is thus submitted that the *in vitro* data provided in the present application is, in view of the above, sufficient to establish practical utility when comparing the results

obtained *in vitro* with the results obtained *in vitro* with metronidazole or tetracycline which are even less effective in the inhibition of *Helicobacter pylori* activity, both of which have shown to be effective in the treatment of *Helicobacter pylori* mediated diseases, i.e., peptic ulcer disease.

Therefore, in view of the above, it is submitted that the present invention is clearly enabled even in the lack of clinical data.

Regarding the portion of the Office action discussing the nature of the invention and the breadth of the claims, the Applicants submit that the nature of the present invention is the finding that antimicrobially active pleuromutilins are also active in the inhibition of *Helicobacter pylori* activity. It is further submitted that the finding is novel, surprising and unexpected. It is also submitted that up to the priority date of the present application (April 23, 2002), it was not known in the prior art that pleuromutilins are active in the inhibition of *Helicobacter pylori* activity. In light of the fact that pleuromutilin is known since at least 1951 (see, for example, F. Kavanagh, et al., PNAS, September 1, 1951, Vol. 37, No. 9 570-574 (copy enclosed)), the Applicant regards the present invention as a milestone invention and, accordingly, the present claims sufficiently encompass the present invention.

In this regard, it is submitted that the presently claimed invention has been deemed patentable in the corresponding European application. Although it is appreciated that the Examiner is not obligated to consider the patentability from a foreign patent office, the Applicants wish to bring this to the Examiner's attention.

In view of the above arguments and amendments, withdrawal of the rejections and objections is respectfully requested.

Conclusion

In light of the foregoing claims and arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: Oct. 28, 2008

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